

2602. Misbranding of Gomco ring pessaries. U. S. v. 17 Devices * * * (and 1 other seizure action). (F. D. C. Nos. 25753, 25764. Sample Nos. 27462-K, 27464-K, 37644-K.)

LIBELS FILED: On or about September 13 and 30, 1948, Eastern District of Missouri and District of Oregon.

ALLEGED SHIPMENT: On or about March 30, May 24, and July 30, 1948, by the Gomco Surgical Manufacturing Corp., from Buffalo, N. Y.

PRODUCT: *Gomco ring pessaries.* 17 devices at St. Louis, Mo., and 20 devices at Klamath Falls, Oreg., together with a number of circulars entitled "Gomco Intrauterine Ring." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a coiled spring.

NATURE OF CHARGE: Misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration recommended and suggested in the circulars, namely, "It may be left in the uterus indefinitely. Cases have been reported in which the ring has been left in position for six years, without removal and with no ill effect. Pathological Tests Give No Indications of Malignancy. We would suggest however that the physician withdraw and place the Gomco Intra-Uterine Ring yearly * * * **Technic:** (As Suggested by Haire) "The Ring Pessary should be inserted during menstrual period in order that one may be certain that patient is not already pregnant. The patient is placed in the lithotomy position, a vaginal speculum is inserted by means of special introducer. There is usually no pain following its introduction and no pain at the periods. Even in cases where menstruation has been painful, previously, the presence of the ring seems to diminish it. **Technic of Gomco Intra-Uterine Ring.** Gomco Intra-Uterine Ring in Uterus (Diagrams showing method of inserting Ring and its position in the Uterus)."

Further misbranding, Section 502 (a), the statements in the circulars "The Gomco Intra-Uterine Ring is used where a * * * safe procedure for contraception is indicated" was false and misleading since the device could not be safely used under any conditions; and, Section 502 (b) (1), the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: October 14 and November 5, 1948. Default decrees of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2603. Misbranding of ring pessaries. U. S. v. 4 Medium ring pessaries, etc. (F. D. C. No. 25742. Sample Nos. 25869-K, 25870-K.)

LIBEL FILED: September 10, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about March 1, 1946, and January 29 and May 3, 1948, by the Gomco Surgical Manufacturing Corp., from Buffalo, N. Y.

PRODUCT: 4 medium and 3 small *ring pessaries* at Minneapolis, Minn. Examination showed that the device was a metallic ring, approximately one inch in diameter which was fashioned from a coiled spring.

*See also Nos. 2601, 2646.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended.

DISPOSITION: January 6, 1949. Default decree of destruction.

2604. Misbranding of Zon-A-Wave Ozone Generator. U. S. v. 12 Devices, etc.
(F. D. C. No. 26003. Sample No. 32306-K.)

LIBEL FILED: December 9, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about September 8, 1948, from Portland, Oreg.

PRODUCT: 12 devices, some of which were labeled "Zon-A-Wave Ozone Generator" and others which were labeled "Portable Ozone Applicator," in the possession of Mrs. Etta H. Gehlen, San Jose, Calif., and certain other persons in Los Gatos, San Jose, and Oakland, Calif., on rental from Mrs. Gehlen. 5,000 pamphlets entitled "Ozone Health Center" and 5 display cards entitled "Pure Ozone is being generated" were also in the possession of Mrs. Gehlen. The pamphlets and display cards were printed in San Jose, on instructions of Mrs. Gehlen. Examination showed that the device was an electrical device which generated ozone.

NATURE OF CHARGE: Misbranding, Section 502 (a), the pamphlets and display cards contained statements which represented and suggested that the devices were effective in the treatment of rheumatism, sinus trouble, neuritis, colds, influenza, stomach trouble, osteomyelitis caused by scarlet fever, severe pain, cough left as an effect of pneumonia, infection, sprained ankle, lame back, varicose veins, chest colds, severe abdominal pains caused by gallstone attack, headache, sinus pains, milk leg, high fever, paralysis from multiple neuritis, continual pain, arthritis, and other kindred ailments, impurities in the blood, and ulcers; that the devices would prevent diseases including tonsillitis, sore throat, colds, headache, stomach-ache, ear-ache, tooth-ache, indigestion, fever, la grippe, and pneumonia; and that the devices would increase efficiency. The devices were not effective in the treatment of the symptoms, diseases, and conditions stated and implied; they would not prevent the diseases and conditions named; and they would not increase efficiency.

Further misbranding, Section 502 (f) (1), the devices bore no directions for use. The devices were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: December 14, 1948. Default decree of condemnation. One device and several copies of the pamphlet and display card were ordered delivered to the Food and Drug Administration, for exhibition in its museum at Washington, D. C., and the remainder of the devices, pamphlets, and display cards were ordered destroyed.

2605. Adulteration and misbranding of elixer of three bromides, tincture of opium camphorated (paregoric), syrup of potassium guaiacolsulfonate, and elixer of terpin hydrate and codeine. U. S. v. David M. Leff (Merit Laboratories Co.). Plea of nolo contendere. Fine, \$700. (F. D. C. No. 25581. Sample Nos. 32-K, 33-K, 52-K, 10425-K, 15156-K.)

INFORMATION FILED: January 25, 1949, Eastern District of Pennsylvania, against David M. Leff, trading as the Merit Laboratories Co., Philadelphia, Pa.

ALLEGED SHIPMENT: Between the approximate dates of February 4 and March 2, 1948, from the State of Pennsylvania into the States of South Carolina, New York, and Michigan.